

BECKMAN

K963976

**Summary of Safety & Effectiveness
IMAGE™ Immunochemistry System Urine Transferrin (TRU) Reagent**

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1.0 Submitted By:

Annette Hellie
Regulatory Specialist, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8767
FAX: (714) 961-4457

2.0 Date Submitted:

30 September 1996

3.0 Device Name(s):

3.1 Proprietary Name

IMAGE™ Immunochemistry System Urine Transferrin (TRU) Reagent

3.2 Classification Name

Transferrin Test System (21 CFR § 866.5880)

4.0 Predicate Device(s):

Beckman Transferrin Kit (Urine application) K926272

5.0 Description:

The IMAGE Immunochemistry System Urine Transferrin (TRU) reagent, in conjunction with Beckman's Urine Protein Calibrator, is intended for use in the quantitative determination of transferrin in human urine samples.

6.0 Intended Use:

The IMAGE Immunochemistry System Urine Transferrin (TRU) reagent, when used in conjunction with Beckman IMAGE™ Immunochemistry Systems and Urine Protein Calibrator, is intended for the quantitative determination of transferrin in urine by rate nephelometry.

Beckman Instruments, Inc.

file: tru510k.sse

twx: 910-592-1260 • telex: 06-78413

Beckman Instruments, Inc., Section 510(k) Notification
 IMAGE™ Immunochemistry System Urine Transferrin (TRU) Reagent
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7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System TRU Reagent	Analytic Range	Same as Beckman Transferrin Kit reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System TRU Reagent	Antigen excess testing	IMMAGE TRU has antigen excess testing solution included in the reagent cartridge, while the Beckman Transferrin Kit requires off-line preparation of the solution.
	Antibody concentration	IMMAGE TRU has a higher antibody concentration than the Beckman Transferrin Kit

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Transferrin Kit Reagent to the IMMAGE TRU Reagent.

Method Comparison Study Results IMMAGE TRU Reagent vs. Beckman Transferrin Kit Reagent

Analyte	Slope	Intercept	r	n	Predicate
IMMAGE TRU	1.111	-0.04	0.998	103	Beckman Transferrin Kit

Stability Study Results

Reagent	Product Claim
IMMAGE TRU	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Within-Run Imprecision

MATERIAL	MEAN (mg/dL)	SD (mg/dL)	%CV	Number of Results
TRU Reagent				
Level 1	0.38	0.010	2.7	80
Level 2	1.55	0.041	2.6	80
Level 3	3.02	0.077	2.6	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.